

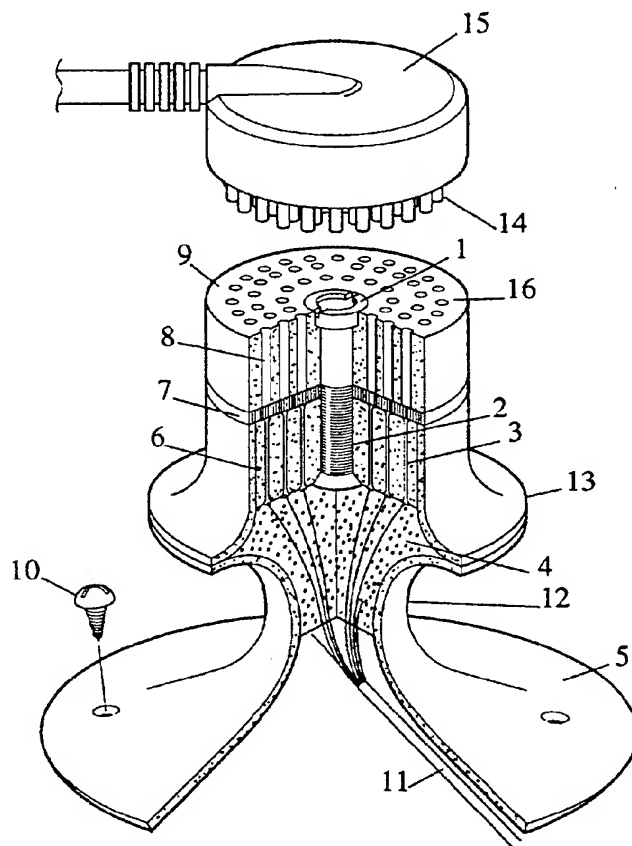


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : H01R 13/514, A61F 11/04	A1	(11) International Publication Number: WO 94/29932 (43) International Publication Date: 22 December 1994 (22.12.94)
(21) International Application Number: PCT/AU94/00310 (22) International Filing Date: 6 June 1994 (06.06.94) (30) Priority Data: PL 9249 7 June 1993 (07.06.93) AU (71) Applicant (for all designated States except US): COCHLEAR PTY. LTD. [AU/AU]; 14 Mars Road, Lane Cove, NSW 2066 (AU). (72) Inventor; and (75) Inventor/Applicant (for US only): KUZMA, Janusz [AU/AU]; 14 Mars Road, Lane Cove, NSW 2066 (AU). (74) Agent: WATERMARK PATENT & TRADEMARK ATTORNEYS; Level 4, Amory Gardens, 2 Cavill Avenue, Ashfield, NSW 2131 (AU).	(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>	

(54) Title: PERCUTANEOUS CONNECTOR SYSTEM**(57) Abstract**

A percutaneous connector system is disclosed for communicating electrical signals between a device implanted within a body, for example a cochlear prosthesis, and an external device. The connector system comprises in a preferred arrangement a base unit (5) affixed to a bone or other structure within the body, a feedthrough unit (9) releasably connected to the base unit (5), and an externally removable component (15). The feedthrough unit (9) and removable component (15) have mating connector sets (14, 16). If the connector sets (14, 16) require replacement through e.g. wear, the feedthrough unit (9) and external component (15) can be replaced without surgical or other trauma to the patient.



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PERCUTANEOUS CONNECTOR SYSTEM

Technical Field

This invention relates to a connector system for use for implanted prosthesis and/or sensor arrangements, including but not limited to cochlear implants and implantable hearing prosthesis systems.

Background Art

It is desirable to provide a convenient and effective system for sending and/or receiving direct electrical signals to or from an implanted device.

Various systems have been used and described in various publications, but all suffer from one or more disadvantages.

A primary requirement is to minimise trauma to the patient, both from the surgical procedure and ongoing during everyday activities.

Avoidance of any infection occurring around the connection is also important. In order to achieve this, it is desirable that components readily subject to wear, such as mating connector parts, can be replaced with minimum inconvenience to the patient.

It is an object of the present invention to provide a percutaneous connector arrangement wherein the mating connector parts may be replaced as necessary with a minimum of trauma to the patient.

20 Summary of the Invention

According to one aspect the present invention provides a percutaneous connector set, comprising:

a base unit adapted to be affixed to an underlying body structure, including a plurality of separate electrical conduction paths extending from a set of contact points on a surface operatively projecting beyond a body, to a set of wires extending within said body;

a feed through unit removably connectable to the base unit, including a set of conduction paths corresponding on one end to the contact points on the base and on the other end to a first part of a detachable connector set; and

an external connector unit including a second part of a detachable connector set.

According to a further aspect the present invention comprises a replaceable connector set operatively adapted to be connected to a base unit affixed to an underlying body structure, said base unit including a plurality of separate electrical conduction paths extending from a set of contact points on a surface projecting beyond a body, to a set of wires extending within said body,

wherein said connector set comprises a feed through unit operatively connectable to the base unit, including a set of conduction paths corresponding on one end to the contact points on said base unit and on the other end to a first part of a detachable connector set, and an external connector unit including a second part of a detachable connector set.

One embodiment of the present invention employs a small, biocompatible pedestal, fixed to the skull and passing through the skin with external, replaceable components attached by means of a screw fixed in the pedestal. The diameter of the base section passing through the skin preferably is of minimal dimension in order to reduce the possibility of passing fluids or bacteria to and from the body. The overall profile of the pedestal is minimised for aesthetic reasons in addition to reducing the disturbance to a patient's everyday activities.

BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 shows in perspective, partly in section, one embodiment of a percutaneous connector system according to the present invention.

DETAILED DESCRIPTION OF DRAWINGS

Referring to Fig. 1, a preferred embodiment of a percutaneous connector system is illustrated. The system may be conveniently described by reference to a number of sub-assemblies whose descriptions are provided below.

There is shown at 1 a threaded fastener which is, for example, a titanium component threaded internally and slotted on the top in order to provide a convenient means of connecting replaceable components to the base unit.

The feedthrough screw 2 is, for instance, made of titanium, and is preferably hermetically sealed within the conductor unit 6 to provide a threaded section for the attachment of the removable connector 9 and the uni-directional conductive washer 7 by means of the threaded fastener 1.

Pins 3, are hermetically sealed within the conductor unit 6 and these provide a means of passing signals to and/or from the internal lead 11.

A biocompatible fixation material 4 (for example Dow Corning MDX-4-4210 Medical Grade Silastic) is preferably filled around the connections to the pins 3 to protect the delicate connections from external forces and disturbances.

It is preferred that pins 3 be formed from a suitable biocompatible conductive material, such as platinum/iridium alloy. Conductor unit 6 is preferably formed from a ceramic material.

The base unit 5 is a critical component of the system and is preferably made of titanium. The lower flanged base is, in a cochlear implant application, preferably attached to the skull by means of four titanium screws 10. It will be appreciated that alternative fixation points and methods of fixation will be appropriate depending upon the devices to which the percutaneous connector is affixed. The neck of the lower flange 12 preferably reduces to a minimal diameter to pass through the skin. This allows for the area around which skin does not regrow to be minimised. On the external side, the diameter is increased to aid in providing a smooth, rounded surface for the skin and tissue to grow around in order to provide a barrier to fluids and bacteria passing to and from the body. Flange 13 provides a mechanical barrier so as to minimise the risk of trauma in use to the regrown area of skin. The upper section hermetically seals the conductor unit 6 and is for example laser welded around the outer edge to the base unit 5.

In order to provide a biocompatible means of passing electrical signals through a barrier impervious to bacteria and fluid, a conductor unit 6 is employed. The conductor unit 6 illustrated contains 64 pins 3 embedded within it. The conductor unit 6 is sealed by, for example, brazing to the base unit 5. To provide a fixation method for the replaceable external components, a platinum tube housing a screw 2 passes through the conductor unit 6. This method provides a hermetical seal across the base of conductor unit 6. The surface of the conductor unit 6 is preferably polished to a mirror finish to maintain a reliable connection to the uni-directional conductive washer 7.

A uni-directional conductive washer 7 is preferably used for connection, and is preferably formed from a commercially available material which provides a convenient and reliable method of connecting the pins 3 of the conductor unit 6 to the pins of the feedthrough 9. The material contains a high density of 5 vertically positioned conductive fibres embedded within an insulating material. This allows for signals to pass perpendicularly to the surface of the material while substantially insulating parallel to the surface.

The feedthrough 9 illustrated contains 64 individual connector sockets 8 for the purpose of connecting to an external plug 15 and transmitting signals to 10 the lower face of the feedthrough 9 for transmission through the uni-directional conductive washer 7 to pins 3. Of course, depending upon the application it may be required for signals to pass in both directions, or the opposite direction, and this is readily implemented with the arrangement shown.

Feedthrough unit 9 contains 64 sockets 8 in an identical pattern to the 15 pins 3 embedded within the conductor unit 6. The connector on the upper side 16 attaches to its opposite gender plug 14 (coming from for example the stimulation source or a monitoring device) and passes the signal through the feedthrough 9 to the lower side where the interface with the uni-directional conductive washer 7 provides a reliable connection to the conductor unit 6 and 20 its pins 3.

It will be appreciated that while the present invention is applicable particularly for cochlear implants, and has been described in this context, it may also be employed wherever signals are required to be sent or received across the skin. It will be understood that variations and additions are possible without 25 departing from the general inventive concept.

CLAIMS

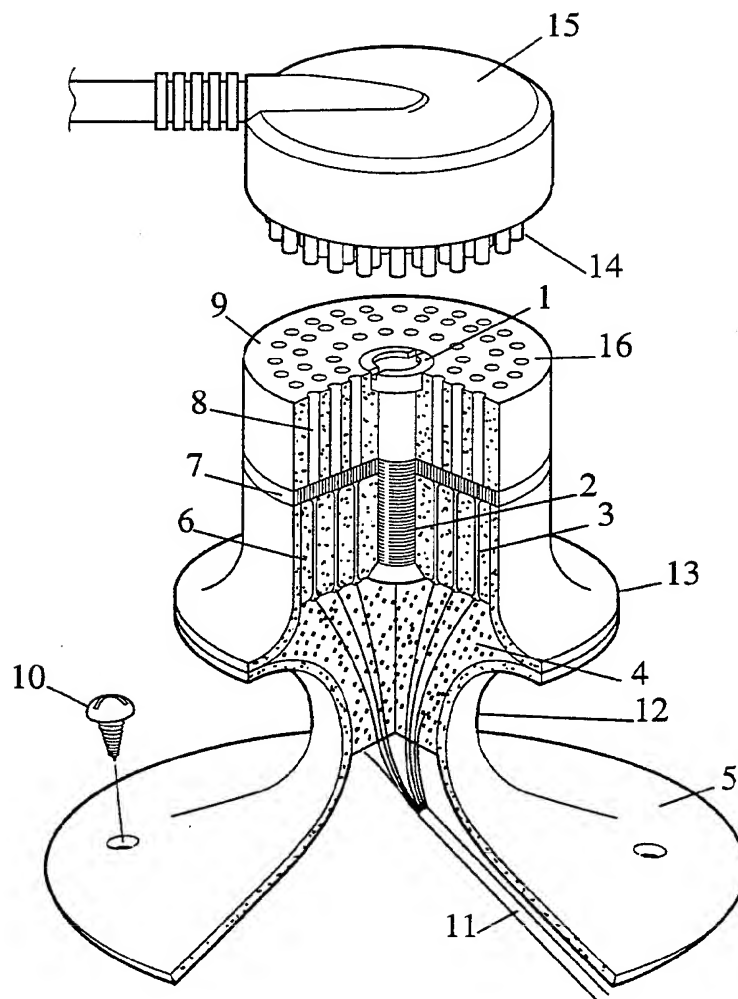
1. A percutaneous connector set, comprising:
 - a base unit adapted to be affixed to an underlying body structure, including a plurality of separate electrical conduction paths extending from a set of contact points on a surface operatively projecting beyond a body, to a set of wires extending within said body;
 - a feedthrough unit removably connectable to the base unit, including a set of conduction paths corresponding on one end to the contact points on the base and on the other end to a first part of a detachable connector set; and
 - an external connector unit including a second part of a detachable connector set.
2. A percutaneous connector set according to claim 1, wherein a conductive washer is provided between the base unit and the feedthrough unit so as to allow connection of said conduction paths, said washer being formed from a material which conducts axially in the direction of connection, but does not substantially conduct in a radial direction.
3. A percutaneous connector set according to claim 1 or claim 2, wherein said feedthrough unit is attached to said base unit by a fastening means positioned substantially along the central axis of said feedthrough unit.
4. A percutaneous connector set according to claim 3, wherein said fastening means comprises a threaded fastener adapted to be rotated from the outer surface of the feedthrough unit, and a projecting screw attached to said base unit.
5. A percutaneous connector set according to any one of the preceding claims, wherein said base unit and said feedthrough unit mate so as to provide a substantially smooth exterior surface.

6. A replaceable connector set operatively adapted to be connected to a base unit affixed to an underlying body structure, said base unit including a plurality of separate electrical conduction paths extending from a set of contact points on a surface projecting beyond a body, to a set of wires extending within said body,

wherein said connector set comprises a feedthrough unit operatively connectable to the base unit, including a set of conduction paths corresponding on one end to the contact points on said base unit and on the other end to a first part of a detachable connector set, and an external connector unit including a second part of a detachable connector set.

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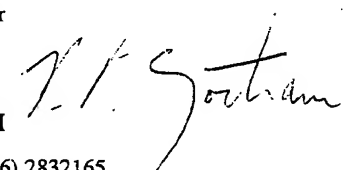
Fig 1.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 94/00310

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. ⁵ H01R 13/514, A61F 11/04 According to International Patent Classification (IPC) or to both national classification and IPC					
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC H01R 13/514, 13/46, 31/06, A61F 11/04, A61N 1/02, 1/372, 1/375, 1/378 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU : IPC as above Electronic data base consulted during the international search (name of data base, and where practicable, search terms used) DERWENT : IPC as above					
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.			
Y	WO,A, 9222107 (COCHLEAR PTY LTD) 10 December 1992 (10.12.92) See whole document including Fig 1-3	1-6			
Y	EP,A, 128472 (LITTON SYSTEMS INC) 19 December 1984 (19.12.84) See Fig 1,2 and description	1-5			
X		6			
Y	EP,A, 484633 (COMBUSTION ENGINEERING INC) 13 May 1992 (13.05.92) See Fig 3 and description	1-6			
(continued)					
<div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. </div> <div> <input checked="" type="checkbox"/> See patent family annex. </div> </div>					
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%; vertical-align: top;"> * Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed </td> <td style="width: 33%; vertical-align: top;"> "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle of theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family </td> <td style="width: 33%;"></td> </tr> </table>			* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle of theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
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Date of the actual completion of the international search 27 September 1994 (27.09.94)	Date of mailing of the international search report 30 SEPTEMBER 1994 (30.09.94)				
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. 06 2853929	Authorized officer  P.F. GOTHAM Telephone No. (06) 2832165				

INTERNATIONAL SEARCH REPORT

International application No.

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate of the relevant passages	Relevant to Claim No.
Y X	FR,A, 2670955 (BERNIER & CIE) 26 June 1992 (26.06.92) See Fig 1-4 and description	1-5 6
Y X	DE,A, 3625196 (KLING) 28 January 1988 (28.01.88) See Fig 1-3 and description	1-5 6
Y X	DE,A, 3042293 (STANDARD ELECTRIC LORENZ) 19 May 1982 (19.05.82) See Fig and description	1-5 6

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member	
WO	9222107	AU	18941/92	EP	587649
EP	128472	JP	60007084		
END OF ANNEX					